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Notice of Allowability	Application No.	Applicant(s)	
	10/736,997	NESS ET AL.	
	Examiner	Art Unit	
	William W. Moore	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the amendment filed 27 November 2006 and the Terminal Disclaimer filed 3 January 2007.

2. ☒ The allowed claim(s) is/are 124,128,129,131,132,142,156 and 161.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of the:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.

(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached

1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.

(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)

2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____

4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material

5. ☐ Notice of Informal Patent Application

6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____

7. ☒ Examiner's Amendment/Comment

8. ☒ Examiner's Statement of Reasons for Allowance

9. ☐ Other _____

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EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In the specification:

Replace the paragraph at page 11, lines 7-13 with the following, amended, paragraph:

In addition, essentially any nucleic acid can be custom ordered from any of a variety of commercial sources, such as The Midland Certified Reagent Company (~~mrcr@oligos.com~~), The Great American Gene Company (~~http://www.genco.com~~), ExpressGen Inc. (~~www.expressgen.com~~), Operon Technologies Inc. (Alameda, CA) and many others. Similarly, peptides and antibodies can be custom ordered from any of a variety of sources, such as PeptidoGenic (~~pkim@ccnet.com~~), HTI Bio-products, Inc. (~~http://www.htibio.com~~), BMA Biomedicals Ltd (U.K.), Bio.Synthesis, Inc., and many others.

Replace the paragraph that spans pages 29 and 30 with the following, amended, paragraph:

Other preferred examples of algorithms that are suitable for determining percent sequence identity or sequence similarity are the BLAST and BLAST 2.0 algorithms, which are described in Altschul et al., (1977) Nuc Acids Res 25:3389-3402 and Altschul et al., (1990) J Mol Biol 215:403-410, respectively. BLAST and BLAST 2.0 are used, with the parameters described herein, to determine percent sequence identity or percent sequence similarity for the nucleic acids and polypeptides and proteins of the invention. Software for performing BLAST analyses is publicly available through the National Center for Biotechnology Information (~~http://www.ncbi.nlm.nih.gov/~~). This algorithm involves first identifying high scoring sequence pairs (HSPs) by identifying

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short words of length W in the query sequence, which either match or satisfy some positive-valued threshold score T when aligned with a word of the same length in a database sequence. T is referred to as the neighborhood word score threshold (Altschul et al., supra). These initial neighborhood word hits act as seeds for initiating searches to find longer HSPs containing them. The word hits are extended in both directions along each sequence for as far as the cumulative alignment score can be increased. Cumulative scores are calculated using, for nucleotide sequences, the parameters M (reward score for a pair of matching residues; always > 0) and N (penalty score for mismatching residues; always < 0). For amino acid sequences, a scoring matrix is used to calculate the cumulative score. Extension of the word hits in each direction are halted when: the cumulative alignment score falls off by the quantity X from its maximum achieved value; the cumulative score goes to zero or below, due to the accumulation of one or more negative-scoring residue alignments; or the end of either sequence is reached. The BLAST algorithm parameters W , T , and X determine the sensitivity and speed of the alignment. The BLASTN program (for nucleotide sequences) uses as defaults a wordlength (W) of 11, an expectation (E) of 10, $M = 5$, $N = -4$ and a comparison of both strands. For amino acid sequences, the BLASTP program uses as defaults a wordlength of 3, and expectation (E) of 10, and the BLOSUM62 scoring matrix (see, Henikoff & Henikoff, (1989) Proc Natl Acad Sci USA 89:10915) uses alignments (B) of 50, expectation (E) of 10, $M = 5$, $N = -4$, and a comparison of both strands. Again, as with other suitable algorithms, the stringency of comparison can be increased until the program identifies only sequences that are more closely related to those in the sequence listings herein (i.e., SEQ ID NO: 1 to SEQ ID NO: 130 or, alternatively, SEQ ID NO: 131 to SEQ ID NO: 260), rather than sequences that are more closely related to other similar sequences such as, e.g., those nucleic

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acid sequences represented by GenBank accession numbers: M65086, D13157, S48754, AB005792, D29688, and M28537 or other similar molecules found in, e.g., GenBank. In other words, the stringency of comparison of the algorithms can be increased so that all known prior art (e.g., those represented by GenBank accession numbers: M65086, D13157, S48754, AB005792, D29688, and M28537 or other similar molecules found in, e.g., GenBank, as well as sequences represented by GenBank accession numbers: P29600, P41362, P29599, P27693, P20724, P41363, P00780, P00781, P35835, P00783, P29142, P04189, P07518, P00782, P04072, P16396, P29140, P29139, P08594, P16588, P11018, P54423, P40903, P23314, P23653, P33295, P42780, and P80146) is excluded.

In the claims:

Cancel claims 130, 133-141, 143-155, and 157-160.

Amend claims 124 and 131 thus:

Claim 124 (Amended). An isolated or recombinant polypeptide having endoprotease activity, which comprises ~~has~~ an amino acid sequence that is at least 97% identical to SEQ ID NO: 134 over a comparison window of SEQ ID NO: 134, wherein the percent amino acid sequence identity is determined using the BLASTP program using the following parameters: a wordlength of 3 and an expectation of 10, and the BLOSUM62 scoring matrix.

Claim 131 (Amended). The polypeptide of claim 124, which is at least ~~about~~ 269 amino acids in length.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Elias J. Lambiris on 8 January 2007.

The following is an examiner's statement of reasons for allowance:

The amendment filed 27 November 2006 overcomes the double-patenting rejection of record over claims of the US Patent No. 6,777,218 to Mikkelsen et al. as well as the

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rejection under 35 U.S.C. § 102(e) of record over the disclosure of Mikkelsen et al. by increasing the degree of amino acid sequence identity with SEQ ID NO:134 required for a claimed protease catalytic domain. Applicant's Terminal Disclaimer filed on 3 January 2007 over the patent term of US 6,902,922 is APPROVED. Claims 138, 140, 146, 148-155, and 157 are canceled in the examiner's amendment because they describe catalytic domain regions that do not meet structural limitations of the amended claim 124 where they share less than 97% identity with SEQ ID NO:134 as determined using the BLASTP program and the specific parameters required by claim 124. Claims 124-137, 139, 141-145, 147, and 156-161 are also canceled because they are co-extensive in scope, raising a separate double-patenting issue, with certain claims of US Patent No. 6,902,922, which issued on the parent application. The examiner's amendment clarifies recitations of claims 124 and 131 so that claim 131 provides a specific limitation of the scope of claim 124 describing members of the genus of claim 124 having an amino acid sequence of as many as 269 amino acids, the size of amino acid sequences of mature *Bacillus lentus* subtilisins, including the subtilisins 147, 309, and PB92. Thus claims 124, 128, 129, 131, 132, 142, 156, and 161 are allowed herewith.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is 571.272.0933 and whose FAX number is 571.273.0933. The examiner can normally be

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reached Monday through Friday between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisory Primary Examiner, Dr. Kathleen Kerr Bragdon, can be reached at 571.272.0931. The official FAX number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571.272.1600.

William W. Moore
8 January 2007


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER